

## REMARKS

### Amendments to the Claims

#### Claim 105

Claim 105 has been amended to include the limitation (i) that the polymorphism in the catalase gene is manifested as a change from a cytosine residue to a thymine residue at nucleotide residue -262, and (ii) that the polymorphism in the superoxide dismutase gene is manifested as a change from a valine residue to a glutamic acid residue at amino acid residue 7 of copper/zinc superoxide dismutase (CZSOD). Support for the amendments to Claim 105 can be found throughout the specification as originally filed, specifically including without limitation (i) page 11, at ¶40; and (ii) cancelled claim 39. Thus, no new matter has been added by way of this amendment. Accordingly, Claim 105, as presently amended, is now pending.

The present amendment reads on the elected invention (Group 3) and is further to the Examiner's 6/20/08 Office Action.

#### Claim 110

Claim 110 is previously presented and reads on the elected invention (Group 3) as it contains the limitations of Claim 105 (presently amended) and is further to the Examiner's 6/20/08 Office Action.

#### Claim 111

Claim 111 has been amended to include the limitation (i) that the polymorphism in the catalase gene is manifested as a change from a cytosine residue to a thymine residue at nucleotide residue -262, and (ii) that the polymorphism in the superoxide

dismutase gene is manifested as a change from a valine residue to a glutamic acid residue at amino acid residue 7 of CZSOD. Support for the amendment to Claim 111 can be found throughout the specification as originally filed, specifically including without limitation (i) page 3, at ¶6; page 11, at ¶ 40; and, (ii) cancelled claim 39. Thus, no new matter has been added by way of this amendment. Accordingly, Claim 111, as presently amended, is now pending.

The present amendment reads on the elected invention (Group 3) and is further to the Examiner's 6/20/08 Office Action.

Claim 112

Claim 110 is previously presented and reads on the elected invention (Group 3) as it contains the limitations of Claim 105 (presently amended) and is further to the Examiner's 6/20/08 Office Action.

Summary of Now-Pending Claims

In light of the foregoing, Claims 105, and 110–112 are now pending in this application following entry of this amendment. Applicants respectfully submit that the now-pending claims are in condition for allowance.

**Election / Restrictions**

In the restriction requirement set forth in the Examiner's 6/20/08 Action, the Examiner identified four (4) Groups of claims, designated Groups 1-4. The Applicants elect Group 3. This election is made with traverse. The Applicants understand that Claim 105 (as originally presented by Amendment dated 3/3/05) has been examined for its full scope.

(See, the Examiner's 6/3/05 Non-Final Office Action, pg. 5)(“Applicants have elected the combination of genes/classes of genes of superoxide dismutase and catalase (claim 105). While this combination of genes and polymorphisms goes beyond the groups set forth in the restriction requirement, claim 105 has been examined for its full scope.”). The claims as previously presented by the Applicants' 4/18/08 Amendment recited assessment of a polymorphism at position -262 of the catalase gene and one of four specific polymorphisms found in a superoxide dismutase gene. The Applicants respectfully point out that, notwithstanding the Examiner's contention that Groups 1-4 represent independent and/or distinct inventions, that each of Groups 1-4 fall within class 435, subclass 6. Accordingly, the Applicants contend that examination of the claims as set forth in their 4/18/08 Amendment would not create undue hardship on the Examiner. Nonetheless, the Applicants aver that the claims as presently amended are congruent with the Examiner's 6/20/08 requirement for restriction pursuant to 35 U.S.C. 121. In particular, the claims are drawn on the elected invention; namely, methods of selecting a dose of anti-oxidant composition by assaying for a polymorphism at position -262 of the catalase gene and a polymorphism at position 7 of copper/zinc superoxide dismutase.

### **Conclusion**

It is respectfully submitted that each of the presently pending claims (105, 110-112) is in condition for allowance and notification to that effect is requested. Further, Applicants respectfully submit that each of the outstanding rejections have been addressed herein and resolved such that the pending claims are in condition for allowance.

The undersigned has made a good faith effort to respond to and overcome all of the rejections in this case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is invited to contact Applicants' undersigned representative if it is believed that prosecution of this application may be assisted thereby. Although only certain arguments regarding patentability are set forth herein, there may be other arguments and reasons why the claimed invention is patentable. Applicants reserve the right to raise these arguments in the future.

The fees believed to be due, if any, have been paid at the time of filing this communication.

Dated: July 21, 2008

Respectfully submitted,  
Applicants John R. DePhillipo, *et al.*,  
By their attorney-of-record,

/Brandy Hill/  
Brandy C. Hill  
Registration No. 51,280  
Customer No. 76953  
Ph: 407.310.5456  
Fx: 407.479.3170  
Em: [bchillpa@earthlink.net](mailto:bchillpa@earthlink.net)

**MARKED-UP COPY OF THE CLAIMS AS AMENDED**  
**(Provided for the Examiner's convenience only)**

1-104. (Cancelled)

105. (Currently Amended) A method of selecting a dose of an anti-oxidant composition for administration to a human, the method comprising assessing an occurrence in a human's genome of a quantity of oxidative damage-associated polymorphisms in each of two genes, the genes consisting of a catalase gene and a superoxide dismutase gene ~~superoxide dismutase gene and a catalase gene~~

wherein the oxidative damage-associated polymorphism in the catalase gene is a polymorphism manifested as a change from a cytosine residue to a thymine residue at nucleotide residue -262 of the catalase gene and the oxidative damage-associated polymorphism in a superoxide dismutase gene is ~~selected from the group consisting of:~~ manifested as a change from a valine residue to a glutamic acid residue at amino acid residue 7 of copper/zinc superoxide dismutase

~~—— a) a polymorphism manifested as a change from an alanine residue to a valine residue at amino acid residue 9 of manganese superoxide dismutase (MnSOD);~~

~~—— b) a polymorphism manifested as a change from an isoleucine residue to a thymine residue at amino acid residue 58 of MnSOD;~~

~~—— c) a polymorphism manifested as a change from a valine residue to a glutamic acid residue at amino acid residue 7 of copper/zinc superoxide dismutase (CZSOD); and~~

~~—— d) a polymorphism manifested as a change from a cysteine residue to a phenylalanine residue at amino acid residue 6 of CZSOD;~~

whereby each occurrence of an oxidative damage-associated polymorphism in each gene indicates an increased susceptibility of the human to a pathology involving oxidative damage to the human, relative to a human with fewer or no oxidative damage-associated polymorphisms.

106-109. (Cancelled)

110. (Previously Presented) The method of claim 105, the method comprising assessing the degree to which a human is susceptible to an undesirable oxidative stress condition by identifying a polymorphism in each of a gene encoding superoxide dismutase, and a gene encoding a catalase,

the polymorphism identified as correlated with the exhibition by a human of a pathology involving oxidative damage, thereafter calculating a susceptibility value for the condition by either

summing the identified polymorphisms to yield a value for the human, or

assigning a weighting factor to each polymorphism and then summing the weighting factors to yield a value for the human,

wherein a value for the human greater than zero indicates a greater susceptibility to the oxidative stress condition for the human,

the method thereby assessing the degree to which the human is susceptible to an undesirable oxidative stress condition relative to a human with fewer or no oxidative damage-associated polymorphisms in these two genes.

111. (Currently Amended) A method comprising assessing occurrence in a human's genome of a quantity of oxidative damage-associated polymorphisms in each of two genes, the genes consisting of a catalase gene and a superoxide dismutase gene ~~and a catalase gene~~,

wherein the oxidative damage-associated polymorphism in the catalase gene is a polymorphism manifested as a change from a cytosine residue to a thymine residue at nucleotide residue -262 of the catalase gene and the oxidative damage-associated polymorphism in a superoxide dismutase gene is ~~selected from the group consisting of:~~ manifested as a change from a valine residue to a glutamic acid residue at amino acid residue 7 of copper/zinc superoxide dismutase

~~—— a) a polymorphism manifested as a change from an alanine residue to a valine residue at amino acid residue 9 of manganese superoxide dismutase (MnSOD);~~

~~—— b) a polymorphism manifested as a change from an isoleucine residue to a thymine residue at amino acid residue 58 of MnSOD;~~

~~—— c) a polymorphism manifested as a change from a valine residue to a glutamic acid residue at amino acid residue 7 of copper/zinc superoxide dismutase (CZSOD); and~~

~~—— d) a polymorphism manifested as a change from a cysteine residue to a phenylalanine residue at amino acid residue 6 of CZSOD;~~

whereby each occurrence of an oxidative damage-associated polymorphism in each gene indicates an increased susceptibility of the human to a pathology involving oxidative damage relative to another human with fewer or no oxidative damage-associated polymorphisms, and thus a desirability to administer an antioxidant composition to the human.

112. (Previously Presented) The method of claim 105, wherein the method assesses a relative susceptibility of the human to the oxidative damage.